Integrated Science Assessments

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Date

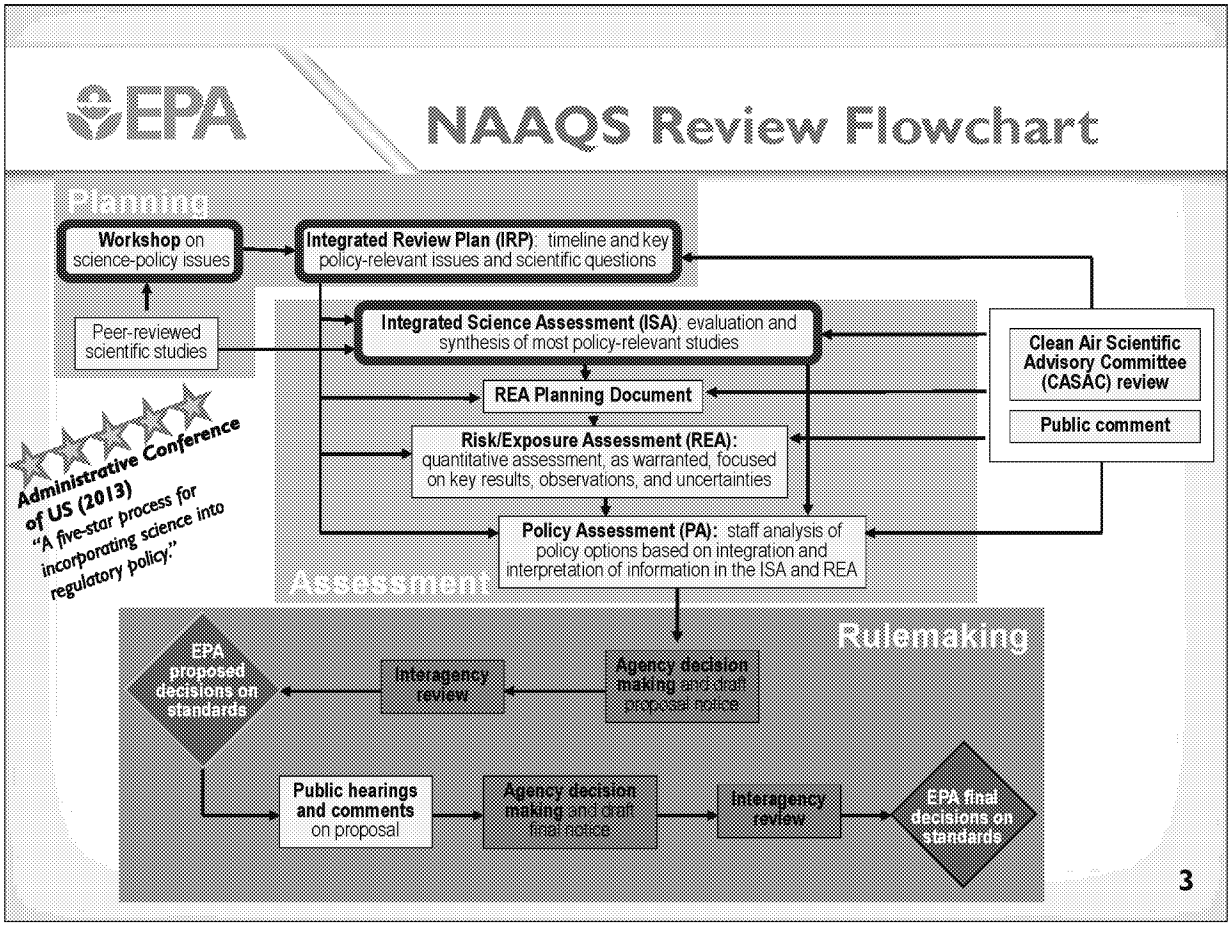
Clean Air Act Requirements

Section 108 of the Clean Air Act requires **"issuance of air quality criteria"** that includes information on "…the **kind and extent of all identifiable effects on public health or welfare** which may be expected from the presence of [the pollutant] in the ambient air…".

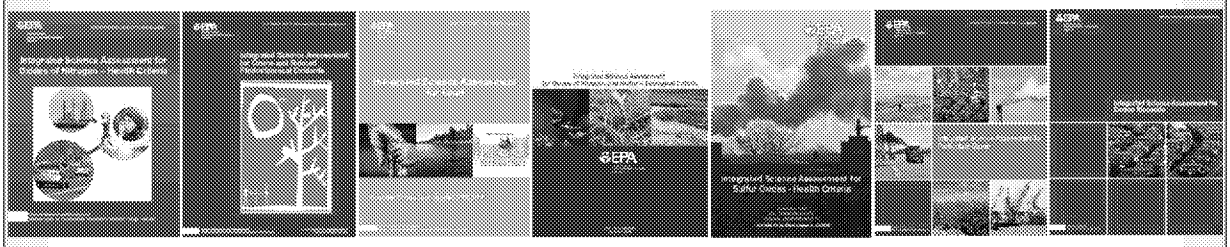
The six criteria air pollutants are: ozone (O_3) particulate matter (PM), sulfur oxides (SOx), nitrogen oxides (NOx), lead (Pb), and carbon monoxide

Section 109 of the Clean Air Act requires for "…any air pollutant for which air quality criteria are issued…" the promulgation of **"…**national primary ambient air quality standards…requisite to protect the public health…" and "…national secondary ambient air quality standard[s]…requisite to protect the public welfare".

The Administrator is charged with promulgating the standards and OAR develops the proposed and final rules with scientific input from ORD.


EPA
NAAQS Review Flowchart
Planning
Workshop on science-policy issues
Integrated Review Plan (IRP): timeline and key policy-relevant issues and scientific questions
Peer-reviewed scientific studies
Integrated Science Assessment (ISA): evaluation and synthesis of most policy-relevant studies
REA Planning Document
Risk/Exposure Assessment (REA): quantitative assessment, as warranted, focused on key results, observations, and uncertainties
Policy Assessment (PA): staff analysis of policy options based on integration and interpretation of information in the ISA and REA
Assessment
Clean Air Scientific Advisory Committee (CASAC) review
Public comment
Administrative Conference of US (2013)
"A five-star process for incorporating science into regulatory policy."
Rulemaking
Agency decision making and draft proposal notice
Interagency review
EPA proposed decisions on standards
Public hearings and comments on proposal
Agency decision making and draft final notice
Interagency review
EPA final decisions on standards
3

The Integrated Science Assessments



- Concise evaluation and synthesis of the most policy-relevant science
- Emphasis on integration of the science and on clear characterization of strengths and uncertainties of available scientific evidence
- **ISA provides the scientific foundation for:**
  - Risk and Exposure Assessment (REA), if warranted
  - Policy Assessment (PA)
  - **Agency decisions as reflected in proposed and final NAAQS rulemaking**
- CASAC reviews the ISA drafts and other documents listed above
  - Public meetings announced in the Federal Register with solicitation for public comments

The ISA Development Process

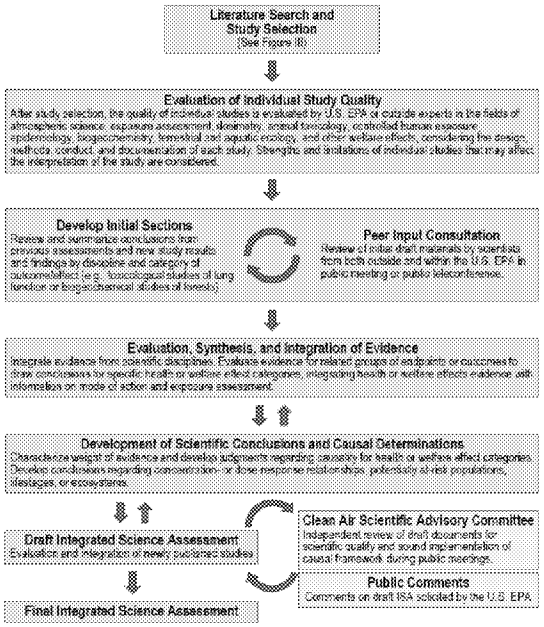


Figure II of the Preamble to the ISA

- Fundamental process:
  - Literature search and study selection
  - Evaluation of individual study quality
  - Evaluation, synthesis, and integration of evidence
  - Development of scientific conclusions and causal determinations
- Several layers of review:
  - Peer input
  - Clean Air Scientific Advisory Committee
  - Public comments
- Typical review cycle includes two drafts and then Final ISA
- **Impact of May 2018 Administrator memo: current PM and Ozone reviews limited to one draft**

Recent Literature Reviews

ISA	Screened	Considered	Included
PM – Health and Welfare Criteria 1st External Review Draft	310,094	5,194	2,655
NO_XSO_XPM – Ecological Criteria 1st External Review Draft	~198,000	~3,200	2,603
SO_X – Health Criteria 2nd External Review Draft	56,502	1,522	1,016
NO_X – Health Criteria Final Report	246,817	5,466	1,680
O_3 – Health and Welfare Criteria Final Report	Not recorded	4,044	2,276
Pb – Health and Ecological Criteria Final Report	~500,000	7,398	3,189

Scientific Evidence: Health Effects

Controlled human exposure studies

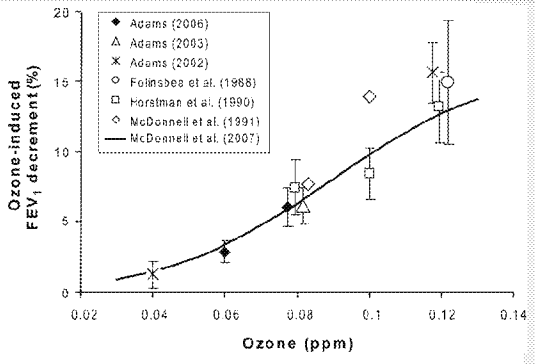
- Direct evidence of a relationship between pollutant exposures and health effects
- Generally small sample size and short exposure time
- Severe health outcomes not assessed
- Predominantly healthy adults

Epidemiologic studies

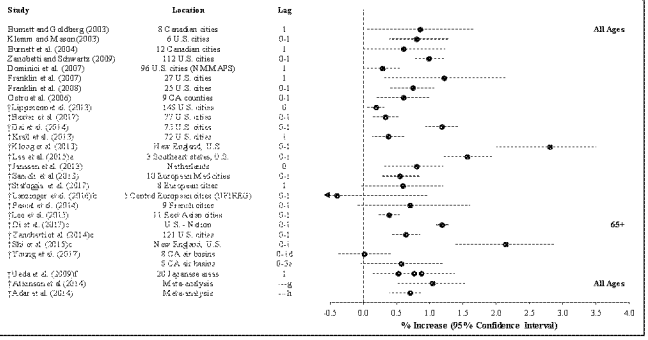
- Some designs include many participants (e.g., millions)
- Natural variation in populations and exposures
- Allows for assessment of potential confounders and uncertainties in the exposure-health relationship

Animal toxicology studies

- Controlled laboratory setting
- Allow exploration of toxicological pathways or mechanisms
- Biological differences among humans and animal species



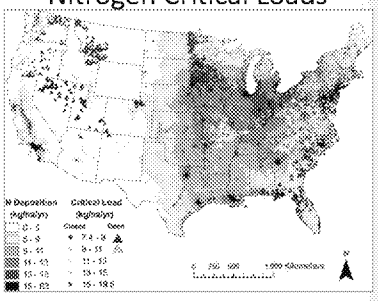
Short-term PM exposure and mortality studies:



Scientific Evidence: Ecological Effects

- **Laboratory studies**
  - More subtle effects easier to detect
  - Limited range of responses and pollutant bioavailability
  - Large scale processes difficult to reproduce
- **Field observational studies**
  - High natural variability
  - Possible to assess multiple stressors or site-specific factors
  - Larger geographic scales or higher levels of biological organization
  - Most effective when stressors and effects are measured concurrently
- **Manipulated natural environments**
  - Some sources of response variation are removed through control conditions
  - Some sources of response variation included to mimic natural variation
  - More controlled than field observational studies
  - Less tightly controlled than laboratory studies

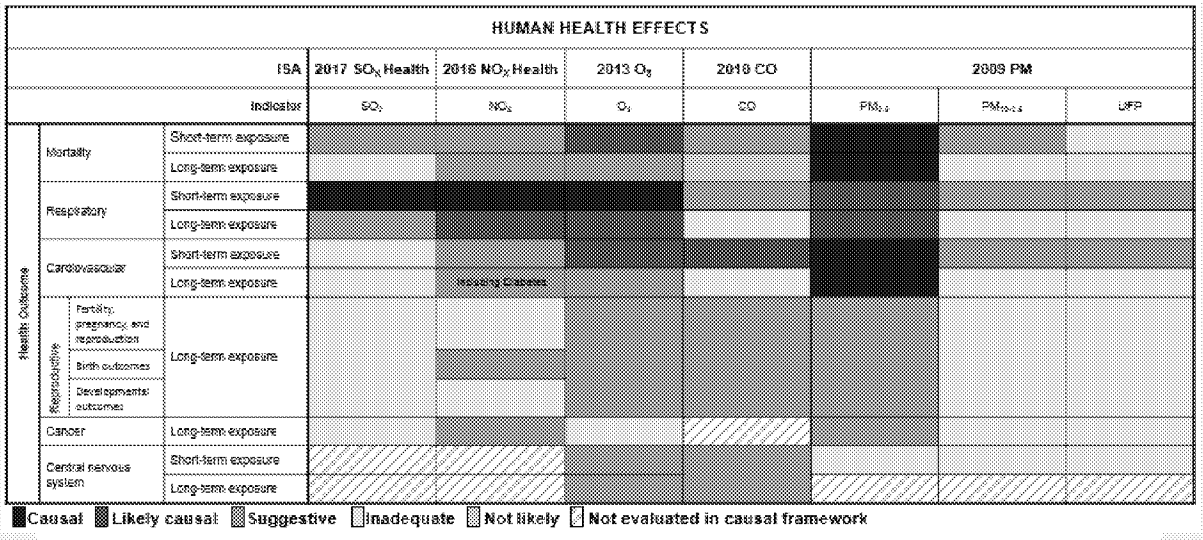
Nitrogen Critical Loads



Framework for Causal Determination

- Promote consistency and transparency
- Emphasize synthesis of evidence across scientific disciplines
- **Weight of evidence categories**:
  - Causal relationship
  - Likely to be a causal relationship
  - Suggestive of, but not sufficient to infer, a causal relationship
  - Inadequate to infer a causal relationship
  - Not likely to be a causal relationship
- ISA Preamble describes this framework
  - Preamble is now stand-alone document (http://www.epa.gov/isa)
- **CASAC has supported use of this framework**

Causality Determinations: Human Health Effects



"All NAAQS All the Time"

Deliberative Process / Ex. 5

*Final rule signature for SO_x by January 28, 2019 by consent decree

Issues for Discussion

- **May 9 2018 Memorandum: "Back to Basics Process for Reviewing the NAAQS"**
  - Accelerate ozone and PM NAAQS reviews; to be completed by December 2020
    - Much less time for ISA development, review, and subsequent NAAQS decision making
    - One draft for CASAC review
  - Resources limited; same staff working on 3 ISAs at same time (PM, Ozone, NOx/SOx/PM-Eco)
  - NOx/SOx/PM-Eco ISA CASAC review meeting held Sept 5-6 2018
  - PM Draft ISA review – December 2018
- **Ozone ISA**
  - Started ISA developent in May 2018; eliminated "kickoff" workshop
  - ISA schedule is integrated with OAR activities (Policy Assessment, Proposed and Final NAAQS)
  - Extremely tight schedule, no room for slippage
- **CASAC**
  - Membership uncertain
  - Timing for PM and Ozone